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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,282	12/20/2001	Paul Young	PZ007G62AP1D1	4789

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/023,282	Applicant(s) YOUNG ET AL.	
	Examiner David J. Blanchard	Art Unit 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 1-85.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 2/25/2005
13. ☐ Other: _____.

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PRIMARY EXAMINER

Continuation of 5. Applicant's reply has overcome the following rejection(s): Claims 76-85 under 35 U.S.C. 112, second paragraph and claims 76-85 under 35 U.S.C. 112, first paragraph, new matter.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments with respect to the rejection of claims 1-85 under 35 U.S.C. 101 have been carefully considered, but have not been found to be persuasive. Applicant argues that the gene encoding the polypeptide of SEQ ID NO:310 is expressed primarily in fetal liver and fetal spleen and the specification discloses that the claimed invention (i.e., antibodies to the polypeptide of SEQ ID NO:310) would be useful in the treatment and/or diagnosis of specific hematopoietic disorders including anemia, pancytopenia, leukopenia and thrombocytopenia (page 14 of response and specification page 99). Applicant argues that Example 2 of the specification (page 430) is an exemplary method by which a disorder may be detected using the polypeptide of the present invention and such characterization of the invention is sufficient to constitute a showing of utility. Applicant continues with arguments directed towards the post filing publications of Liu et al and US 2003/0082184 A1 as well as the art of Krause et al for support of the asserted utilities.

The utility proffered by applicant is not a substantial utility and there is no well-established utility for the polypeptide of SEQ ID NO:310 and antibodies that bind thereto. The asserted utility in the specifiation is preliminary at best and is based on the tissue distribution of the gene encoding the polypetpide of SEQ ID NO:310 in fetal liver and fetal spleen, not the expression of the polypeptide to which the claimd antibodies bind. With respect to the polypeptide of SEQ ID NO:310, the specification asserts that "expression within fetal tissue indicates that this protein may play a role in the regulation of cellular division, and may show utility in the diagnosis and treatment of cancer and other proliferative disorders" and because developmental tissues rely on decisions involving cell differentiation and/or apoptosis, the specification asserts that "the protein may also be involved in apoptosis or tissue differentiation and could again be useful in cancer therapy." (see page 99, lines 17-24). Clearly the specification speculates as to the possible practical uses of the polypeptide and antibodies that bind thereto, however, this is merely an invitation to experiment as the utility of the claimed invention. The specification as-filed does not identify or characterize the polypeptide of SEQ ID NO:310 in terms of its regulation, expression, activity or functional/biological significance in any of the disclosed disorders. Applicant merely speculates that based on the expression of the gene encoding the polyepptide of SEQ ID NO:310 in developmental tissue, that the polypeptide of SEQ ID NO:310 may play a role in cellular division and may have therapeutic use in the diagnosis and treatment of cancer and proliferative disorders. Further, example 22 at page 430 merely represents a prophetic example for detecting abnormal levels of a polypeptide in a bioliogcal sample, which again is an invitation for further research into the utility of the claimed invention. One skilled in the art would not know whether the polypeptide of SEQ ID NO:310 increases or decreases in any of the disclsosed conditions or what significance the increase or decrease has. Thus, one skilled in the art would have to carry out further research to identify a "real world" context of use and therefore, the asserted utilities are not substantial. Applicant's arguments with respect to the post-filing publications and the art of Krause et al are insufficient to overcome the instant utility rejection because it is applicant's specification that must support patentable utility of the claimed invention. Applicant argues that "an equation of the proper legal requirement of "specific utility" with a "unique utility" is improper" and applicant reiterates that the polypeptide of the present invention is preferentially expressed in CD34+ hematopoietic cells and therefore may be used specifically to measure levels of hematopoietic stem/progenitor cells in biological samples and treat and/or diagnose disorders associated with altered levels of such cells. Again, this asserted utility is speculative at best and requires further experimentation. Further, applicant's disclsoure only establishes expression of the gene encoding the polypeptide of SEQ ID NO:310 in fetal liver and spleen and does not support the expression of the polypeptide in these tissues, much less in CD34+ cells. Applicant's reference to Newman v. Quigg is acknowledged, however, the instant rejection is based on lack of substantial utiltiy where operability is not in question. The facts in Newman v. Quigg are based on lack of utility where operability of the claimed invention was in question. Therefore, for reasons of record and reiterated herein, the asserted utilities in applicant's specification are not supported by a substantiial utility or a well-established utility and the rejection is maintained.

Further, since the claimed invention is not supported by a substantial utility or a well-established utiltiy for reasons of record and reiterated above, one skilled in the art clearly would not know how to use the claiemd invention. Thus, the rejection of claims 1-85 under 35 U.S.C. 112, first paragraph, is also maintained.

The rejection of claims 1-85 under 35 U.S.C. 112, first paragraph, for lack of enablement is maintained for reasons of record. Applicant argues that the enablement requirement requires nothing more than objective enablement and the specification need only to enable a person of ordinary skill in the art to practice the claimed invention without undue experimentation and the issue is not whether the specification provides proof that HEMAE80 (SEQ ID NO:310) is overexpressed or underexpressed in hematopoietic disorders, but rather whether the uses involving the claiemd antibodies that bind the HEMAE80 polypeptide of SEQ ID NO:310 can be confirmed without undue experimentation following the procedures either described in the specification or otherwise known in the art. In response to these arguments, the expression of the HEMAE80 polypeptide is directly linked to the enablement of the asserted diagnostic/therapeutic uses disclosed in the specification. The specification has not enabled any uses of the HEMAE80 polypeptide or antibodies that bind thereto and one skilled in the art cannot predictably extrapolate the limited gene expression data in fetal liver and fetal spleen to the expression of the HEMAE80 polypeptide in the various hematopoietic disorders with a reasonable expectation of success in view of the art of record (i.e., Fu, Powell, Lewin, Jang, Alberts and Gokman-Polar). The art of record evinces that nucleic acid expression is not predictive of the expression of the corresponding polypeptide. Further, the specification does not teach any activity of the HEMAE80 polypeptide or whether the HEMAE80 polypeptide to which the claimed antibodies are directed would be overexpressed or underexpressed in a hematopoietic disorder or even what functional significance the aberrant expression of the HEMAE80 polypeptide would have. The response also argues that the examiners comments in the previous Office Action at page 9 with respect to working examples is contrary to well-established law and to require such a complete disclsoure would necessitate a patent with thousands of examples. In response to this argument, applicant appears to have taken the examiners comment out of context. The examiner acknowledges that enablement of the claimed invention does not turn on whether or not applicant discloses a working example (MPEP 2164.02). The comment was made in the conclusion of of the enablement rejection (page 9 of the previous Office Action) in the context of the overall analysis of the Wands factors with respect to the predictability of practicing the claimed invention with a reasonable expectation of success. Applicant is

not required to have any working examples, however, the presence or absence of working examples is one of the Wands factors that is considered for enablement of the claimed invention. The MPEP makes clear that the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art, wherein the amount of guidance and direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention (MPEP 2164.03). The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction.

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